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DEPT FOR EB/TPP/ABT, OES/PCI, AND AF/S
DEPT PASS EB/TPP/ABT - JBOBO, JFINN, GCLEMENTS, AND MKOCH
USDA FAS FOR OSTA/NTPMB/MHENNEY AND FNAIM
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SUBJECT: READOUT OF SOUTH AFRICAN BIOTECHNOLOGY OUTREACH EVENTS

REF: A) STATE 160639 B) PRET 000004

Summary

¶1. SUMMARY From September 15 - 19, Dr. Chris Wozniak, Biotechnology Special Assistant, U.S. Environmental Protection Agency (EPA), was in South Africa under the auspices of the State/EB agricultural biotechnology outreach program to make presentations on the U.S. coordinated framework and risk analyses and assessments to South Africa's GMO Biotechnology Advisory Committee and Subcommittee members, government partners, and stakeholders . The visit of Dr. Wozniak was funded by State/EB funds. USDA/FAS supplemented these funds with $12,000 and provided a second speaker for this trip, Dr. Robyn Rose, USDA/Animal Plant Health Inspection Service (APHIS).

¶2. Drs. Wozniak and Rose's trip included two one-day presentations to new members of the South African GMO Advisory committees and subcommittees as well as presentations at the Bio2Biz biotechnology forum sponsored by the South African Department of Science and Technology and presentations at the International Centre for Genetic Engineering and Biotechnology's (ICGEB) Biosafety course. END SUMMARY.

Advisory Committee and Subcommittee

¶2. The GMO Advisory Committees (AC) are panels of independent experts that review and evaluate all applications for GMOs. Their evaluation is written up as a decision memo to the Executive Council (EC), who makes the final approval decision on the application. During the review by the AC, there may be subcommittees established to look at particular aspects of the application. During a recent review of Advisory Committee and Subcommittee expertise, several areas of deficiencies were identified. The deficiencies were addressed by increasing the number of Advisory Committee and Subcommittee members and widening the disciplines represented.

¶3. Drs. Wozniak and Rose were invited by the South African Directorate of Biosafety of the National Department of Agriculture to be international expert speakers at a workshop aimed at new entrants to the Advisory Committees and Sub-Committees. The new entrants come from research institutes, universities, and government institutions. This two-day workshop was held in Pretoria and in Cape Town. Drs. Wozniak and Rose led the first day of the workshop, focused on risk analyses and assessments, in both locales.

¶4. The format in Pretoria and Cape Town were similar, but there were noticeable differences in audience participation, interest, and interaction. In both workshops, Drs. Wozniak and Rose presented on the U.S. Coordinated Framework, to bring into context the reasons why the USG focuses on certain areas of risk assessments. Each speaker focused on his or her specialty areas; Dr. Wozniak spoke of the EPA's role in regulation of genetically engineered organisms

(GEO) and Dr. Rose focused on APHIS' role. After an initial introduction to the U.S regulatory system, Dr. Wozniak spoke on the basics of risk assessment, specifics of risk assessment of plant incorporated pesticides, and risk communication. Dr. Rose spoke on the role of APHIS in the regulatory process, insect resistance management, and ecological risk assessments.

¶5. In most instances members of the AC and Sub AC are also employed in other capacities, usually as professors or university Qin other capacities, usually as professors or university researchers, unlike in the United States where full time staff handles most, if not all, of the regulatory matters needed to approve a crop for field release and/ or commercialization. Therefore, the actual time AC and Sub AC members have available to conduct a thorough review of documentation to provide a recommendation to the Executive Council, could be limited depending on workload from their primary employment.

¶6. The audience in Pretoria was made up of representatives from the research community, universities, private industry, and government. All participants were PhDs with expertise including veterinary science, ecology, molecular biology, pharmacology, biochemistry, genetics, and biotechnology. The Cape Town audience was made up mostly of academia, all PhDs, with several from the medical community. The audience in Cape Town was more engaged and entered into livelier discussions with the speakers. The format was identical to Pretoria, but there were many more questions and discussions with the speakers.

¶7. The participants interacted with the speakers and asked questions that demonstrated differences in viewpoints involving environmental issues and methodologies for assessing the state of

any particular area (e.g. fields, grasslands, etc). Specifically, there was a concern that the United States should survey the environment for various ill described parameters to look for subtle effects of GEOs. The same participant expressed concern for food safety aspects of genetically engineered (GE) crops, overall. Additional concerns from AC members focused more on logistical or practical issues involving completing a review or experiment and determining what types of data needed to be gathered for risk assessment. Overall, the speakers saw a definite confidence in the different audiences relative to the use of GE technology in agriculture.

¶8. Many participants in attendance took something away from the training, even if it was just an affirmation of the South African process through contrast with the United States.

¶9. Since the workshop in Pretoria, several participants have contacted Drs. Rose and Wozniak with further questions and requests for guidance. Both speakers have expressed their interest in continuing the dialogue with their South African counterparts, and genuinely are interested in providing the information they have access to further the work of the AC.

¶10. Comment. South African agriculture, cultural practices, and regulatory processes are distinctly different from the United States, and the approval process of the United States should not and will not be a perfect fit for the South Africa. However, there are parts of our process that do make sense to be incorporated in the South African process i.e., allergenicity studies, and other issues that are the same between the two countries. But there are also vast differences in production practices that dictate the use of certain methodologies in the United States that would not be appropriate in South Africa. For example, the United States' Midwest can be characterized as a corn monoculture; therefore insect resistance management is an issue that needs to be addressed in order to ensure the GE events that are introduced in the area continue to perform efficiently and do not result in the creation of insect resistance. In South Africa, however, there are no monocultures to the extent of the Midwest in the United States. Therefore, the expense of incorporating and managing insect resistance management practices in South Africa would far outweigh

any benefit gained. End Comment

Bio2Biz

¶11. Dr. Wozniak was present at the 2008 Bio2Biz technology forum in Johannesburg on Tuesday, Sept 16, 2008. He sat on a panel for Health Biotech in Developing Countries where he spoke on plant incorporated protectants and risk assessments in EPA. The conference was a bit disorganized and audience participation was at a minimum.

ICGEB

¶12. Both speakers also participated as speakers at the biosafety course entitled "Benefits, Opportunities, and Risks from the Release of GMOs in Africa" offered by the Cape Town component of the International Centre for Genetic Engineering and Biotechnology (ICGEB). This course was sponsored by the ICGEB, Biosafety South Africa, CSIR, Italian Ministry of the Environment, and Institute of Plant Biotechnology for Developing Countries of the University of Gent, Belgium. It was held during the week of September 15 -19. QGent, Belgium. It was held during the week of September 15 -19. Over 40 people from all over the world, including Egypt, Zimbabwe, Nigeria, Kenya, Colombia, Peru, Namibia, Uganda, South Africa, Cameroon, and Italy participated in the course. Drs. Wozniak and Rose participated on September 18th and 19th. USDA/FAS also sponsored the participation of Dr. Hector Quemada, Calvin College, Michigan. Dr. Rose presented on the coordinated framework of the United States, the role of APHIS in the process, and insect resistance management. Dr. Wozniak spoke on post gene flow risk assessments, viral coat proteins, and RNAi- based mechanisms. Dr. Quemada participated throughout the week and made special presentations on the risk analysis with hands-on exercises on the evaluation of transgenic squash.

¶13. The presence of these three speakers from the United States was particularly important as many of the other instructors were from Europe. Although the European speakers were not overtly against biotech, there were noticeable differences between their perspective of risk analysis and risk communication and those of the American speakers. The contributions of the American delegation provided a

balance to the workshop's agenda that the audience would not have received without the USG participation.

Future Activities

¶14. Both trainings were comprehensive in explaining the main aspects of the United States regulatory system. Many issues were not discussed that are of equal importance, including data submission, formatting, record keeping, confidentiality, review and maintenance fees, dockets, and other paper work that can be critical to a sustainable system and adherence to statutes. South Africa has shown definite movement in the past month towards a mandatory GE labeling requirement which will rely significantly on monitoring and enforcement, two additional issues South Africa will need to focus on to ensure compliance. South Africa would also benefit from further training in USDA/GIPSA sampling and monitoring for unapproved events in grain and soy imports or exports as well as the role the FDA consultation process and its impact in the approval process.

Background

¶15. South African biotechnology policy is formulated under the Genetically Modified Organisms (GMO) Act of 1997. This act was modified by Cabinet in 2005 to bring it in line with the Cartagena Biosafety Protocol (CBP) and again in 2006 in order to address some economic and environmental concerns. These amendments were published and gazetted on April 17, 2007. Implementing guidelines

have not yet been published. These amendments are said to be administrative in nature, but there a few substantive changes that may impact the current biosafety regulatory system.

Increase in EC Representatives

¶16. Executive Council (EC) membership, which is responsible for making regulatory decisions, was increased from six to eight members by adding representatives from the Department of Arts and Culture and the Department of Water Affairs and Forestry. Currently, the EC is made up of the following representatives: Department of Agriculture, Department of Science and Technology, Department of Environment and Tourism, Department of Trade and Industry, Department of Health; and, Department of Labor.

¶17. Comment. The addition of two new representatives to the EC may be only administrative, but it could potentially impact the work of the EC. The new representatives may not have significant knowledge of biotechnology and biosafety, nor have any interest in the subject. It may also be more difficult to get a quorum to have an EC meeting and to reach consensus decisions because the EC functions by consensus and each member has the right to veto a decision he or she does not endorse. This could delay decisions on permit applications. End comment.

Other Potentially Significant Changes to the Current Law

¶18. One other amendment to the GMO Act authorizes the EC to determine if an environmental impact assessment (EIA) is required under the National Environmental Management Act, giving the EC significant power to decide if a costly and potentially time-consuming Environmental Impact Assessment is required. If one representative of the EC wants an EIA done, it will be required since the EC works on consensus.

¶19. The amendments also add specific legislation to allow
Q19. The amendments also add specific legislation to allow socio-economic considerations to factor into decision-making and makes those considerations significantly important in the decision making process. A final change that could impact the GMO approval process is a statement in the GMO Amendments Act that declares that a summary of the scientifically-based risk assessment on environmental and human/animal health impact cannot be kept confidential. Releasing this information to the public may provide more transparency and public participation, but could also add cost and time to the regulatory process for the applicants and the Registrar.

National Environmental Management Biodiversity Act

¶20. The 2004 National Environmental Management Biodiversity Act

(NMBA) protects South Africa's biodiversity from specific threats, and includes GMOs as one as those threats. NMBA also ensures there is a sharing of benefits from South Africa's biological resources. NMBA Section 78 gives the DEAT Minister power to deny a permit for general or trial release applied for under the GMO Act, if that GMO may pose a threat to any indigenous species or the environment, unless an environmental assessment has been conducted.

¶21. Few GMO environmental assessments have been conducted as a result of the NMBA requirements. However, if the Minister deems it necessary, and the criteria for that decision are not clear, an expensive and time-consuming process would have to be completed before the EC could move forward with the GMO permit application.

¶28. Comment. NMBA has changed DEAT's role in the EC. This new responsibility to ensure that GMOs are correctly assessed and do not pose a risk to the environment has forced them to ask more pointed questions and request more data before deciding on the status of new GMO permits. End Comment.